# CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

**Application Number : 040105**

**Trade Name : OXYCODONE AND ACETAMINOPHEN TABLETS USP 5MG/325MG**

**Generic Name: Oxycodone and Acetaminophen Tablets USP 5mg/325mg**

**Sponsor : Vintage Pharmaceuticals, Inc.**

**Approval Date: July 30, 1996**

# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION 040105

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| | Included | Pending Completion | Not Prepared | Not Required |
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| **Approval Letter** | X | | | |
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| **Approvable Letter** | | | | |
| **Final Printed Labeling** | X | | | |
| **Medical Review(s)** | | | | |
| **Chemistry Review(s)** | X | | | |
| **EA/FONSI** | | | | |
| **Pharmacology Review(s)** | | | | |
| **Statistical Review(s)** | | | | |
| **Microbiology Review(s)** | | | | |
| **Clinical Pharmacology Biopharmaceutics Review(s)** | | | | |
| **Bioequivalence Review(s)** | X | | | |
| **Administrative Document(s)** | | | | |
| **Correspondence** | | | | |
| | | | | |

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Application Number 040105

## APPROVAL LETTER

ANDA 40-105

JUL 30 1996

Vintage Pharmaceuticals, Inc.
Attention: Rebecca A. Thurman
3241 Woodpark Boulevard
Charlotte, NC 28206

Dear Madam:

This is in reference to your abbreviated new drug application dated June 9, 1994, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Oxycodone and Acetaminophen Tablets USP, 5 mg (as Oxycodone Hydrochloride)/ 325 mg.

Reference is also made to your amendments dated April 30, 1996, May 30, 1996, June 10, 1996, June 20, 1996, July 8, 1996 and July 16, 1996.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Oxycodone and Acetaminophen Tablets USP, 5 mg (as Oxycodone Hydrochloride)/325 mg, to be bioequivalent and, therefore, therapeutically equivalent to those of the listed drug (Percocet® Tablets, of Dupont Merck Pharmaceutical Co.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

/S/ 7/30/96

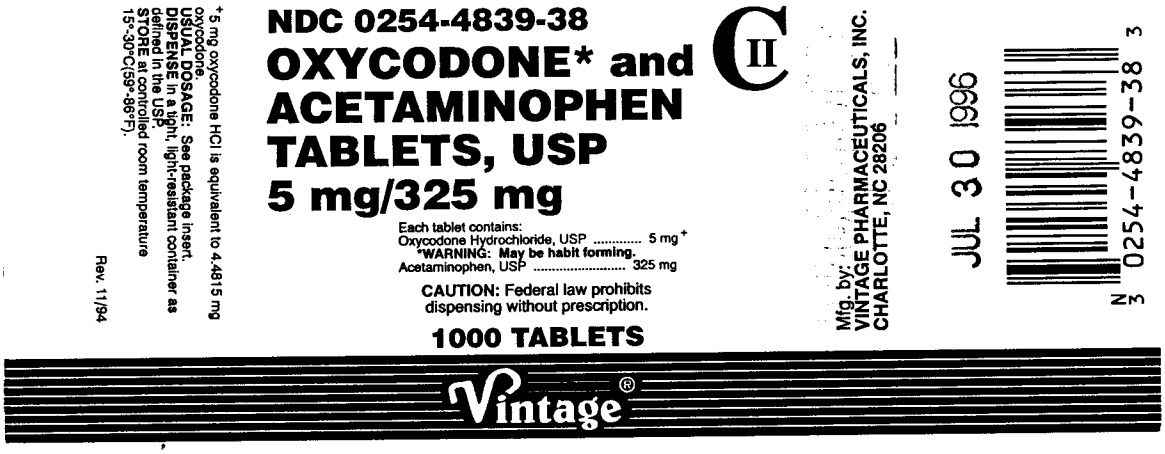
Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

# CENTER FOR DRUG EVALUATION AND RESEARCH

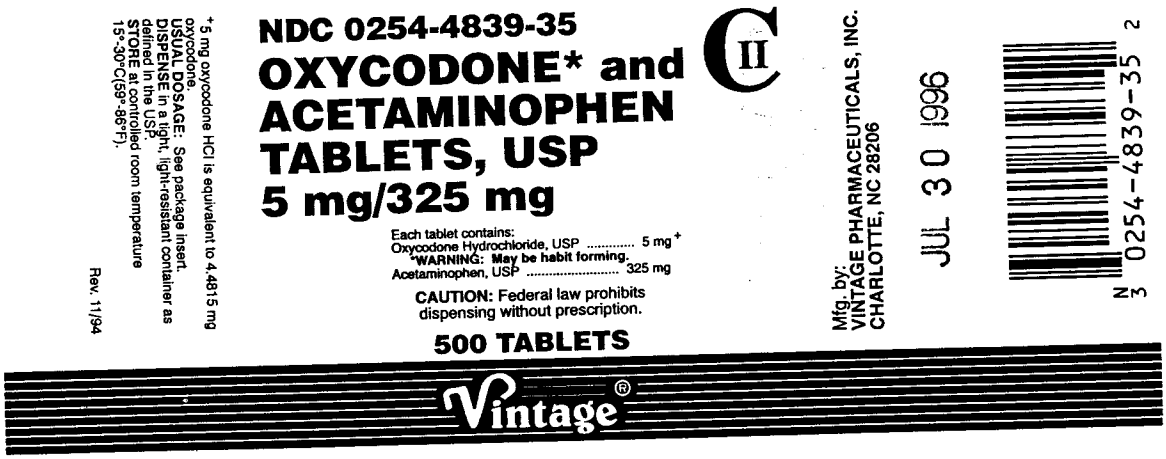
## APPLICATION NUMBER 040105

## FINAL PRINTED LABELING

VINTAGE PHARMACEUTICALS, INC
Oxycodone and Acetaminophen Tablets, USP
5 mg (as Oxycodone Hydrochloride)/325 mg
Major Amendment

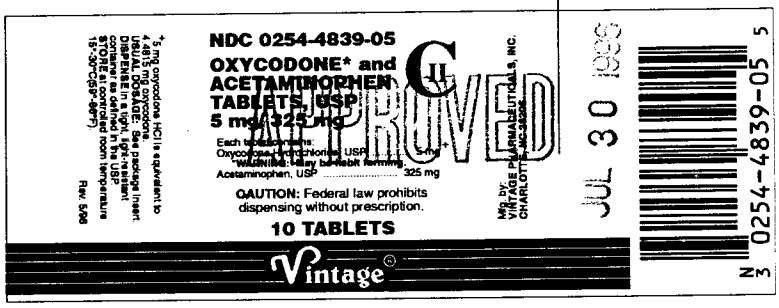


VINTAGE PHARMACEUTICALS, INC
Oxycodone and Acetaminophen Tablets, USP
5 mg (as Oxycodone Hydrochloride)/325 mg
Major Amendment



VINTAGE PHARMACEUTICALS, INC
Oxycodone and Acetaminophen Tablets, USP
5 mg (as Oxycodone Hydrochloride)/325 mg
Major Amendment

NON-VARNISH




LABEL SIZE 1 1/2 X 4 INCHES

# OXYCODONE* AND ACETAMINOPHEN TABLETS, USP

C II

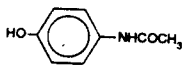
## DESCRIPTION

Each tablet, for oral administration, contains:

| | |
|---|---|
| Oxycodone hydrochloride (equivalent to 4.4815 mg. of Oxycodone) | 5 mg |
| *WARNING: May be habit forming | |
| Acetaminophen, USP | 325 mg |

In addition each tablet contains the following inactive ingredients: crospovidone, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized corn starch, sodium starch glycolate and stearic acid.

The acetaminophen component is 4'-hydroxyacetanilide, a white, odorless, crystalline powder possessing a slightly bitter taste, and is represented by the following structural formula:

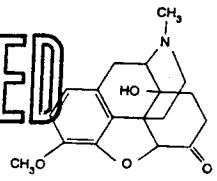



$C_8H_9NO_2$

MW = 151.16

The oxycodone component is 14-hydroxydihydrocodeinone, a white, odorless, crystalline powder having a saline, bitter taste. It is derived from the opium alkaloid thebaine, and may be represented by the following structural formula:






$C_{18}H_{21}NO_4$

MW = 315.37

## CLINICAL PHARMACOLOGY

The principal ingredient, oxycodone, is a semisynthetic narcotic analgesic with multiple actions qualitatively similar to those of morphine; the most prominent of these involve the central nervous system and organs composed of smooth muscle. The principal actions of therapeutic value of the oxycodone in this product are analgesia and sedation.

Oxycodone is similar to codeine and methadone in that it retains at least one-half of its analgesic activity when administered orally.

Acetaminophen is a non-opiate, non-salicylate analgesic and antipyretic.

## INDICATIONS AND USAGE

Oxycodone and Acetaminophen Tablets, are indicated for the relief of moderate to moderately severe pain.

## CONTRAINDICATIONS

Oxycodone and Acetaminophen Tablets, should not be administered to patients who are hypersensitive to oxycodone or acetaminophen.

## WARNINGS

**Drug Dependence:** Oxycodone can produce drug dependence of the morphine type and, therefore, has the potential for being abused. Psychic dependence, physical dependence and tolerance may develop upon repeated administration of Oxycodone and Acetaminophen Tablets, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic-containing medications. Like other narcotic-containing medications, Oxycodone and Acetaminophen Tablets, are subject to the Federal Controlled Substances Act (Schedule II).

## PRECAUTIONS

### General

*Head Injury and Increased Intracranial Pressure:* The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries.

*Acute Abdominal Conditions:* The administration of products containing oxycodone or other narcotics may obscure the diagnosis or clinical course in patients with acute abdominal conditions.

*Special Risk Patients:* Oxycodone and Acetaminophen Tablets, should be given with caution to certain patients such as the elderly or debilitated, and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, and prostatic hypertrophy or urethral stricture.

### Information for Patients

Oxycodone may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using Oxycodone and Acetaminophen Tablets should be cautioned accordingly.

### Drug Interactions

Patients receiving other narcotic analgesics, general anesthetics, phenothiazines, other tranquilizers, sedative-hypnotics or other CNS depressants (including alcohol) concomitantly with Oxycodone and Acetaminophen Tablets may exhibit an additive CNS depression. When such combined therapy is contemplated, the dose of one or both agents should be reduced.

The concurrent use of anticholinergics with narcotics may produce paralytic ileus.

### Pregnancy

*Teratogenic Effects: Pregnancy Category C:* Animal reproductive studies have not been conducted with Oxycodone and Acetaminophen Tablets. It is also not known whether Oxycodone and Acetaminophen Tablets can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Oxycodone and Acetaminophen Tablets should not be given to a pregnant woman unless in the judgment of the physician, the potential benefits outweigh the possible hazards.

*Nonteratogenic Effects:* Use of narcotics during pregnancy may produce physical dependence in the neonate.

**Labor and Delivery:** As with all narcotics, administration of Oxycodone and Acetaminophen Tablets to the mother shortly before delivery may result in some degree of respiratory depression in the newborn and the mother, especially if higher doses are used.

**Nursing Mothers**

It is not known whether the components of this product are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Oxycodone and Acetaminophen Tablets are administered to a nursing woman.

**Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

## ADVERSE REACTIONS

The most frequently observed adverse reactions include lightheadedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients, and some of these adverse reactions may be alleviated if the patient lies down.

Other adverse reactions include euphoria, dysphoria, constipation, skin rash and pruritus. At higher doses, oxycodone has most of the disadvantages of morphine including respiratory depression.

## DRUG ABUSE AND DEPENDENCE

Oxycodone and Acetaminophen Tablets are a Schedule II controlled substance.

Oxycodone can produce drug dependence and has the potential for being abused. (See WARNINGS)

## OVERDOSAGE

**Acetaminophen**

**Signs and Symptoms:** In acute acetaminophen overdosage, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma and thrombocytopenia may also occur.

In adults, hepatic toxicity has rarely been reported with acute overdoses of less than 10 grams and fatalities with less than 15 grams. Importantly, young children seem to be more resistant than adults to the hepatotoxic effect of an acetaminophen overdose. Despite this, the measures outlined below should be initiated in any adult or child suspected of having ingested an acetaminophen overdose.

Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.

**Treatment:** The stomach should be emptied promptly by lavage or by induction of emesis with syrup of ipecac. Patient's estimates of the quantity of a drug ingested are notoriously unreliable. Therefore, if an acetaminophen overdose is suspected, a serum acetaminophen assay should be obtained as early as possible, but no sooner than four hours following ingestion. Liver function studies should be obtained initially and repeated at 24-hour intervals.

The antidote, N-acetylcysteine, should be administered as early as possible, preferably within 16 hours of the overdose ingestion for optimal results, but in any case, within 24 hours. Following recovery, there are no residual, structural, or functional hepatic abnormalities.

**Oxycodone**

**Signs and Symptoms:** Serious overdosage with oxycodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.

**Treatment:** Primary attention should be given to the reestablishment of adequate respiratory exchange through provision of a patent airway and the institution of assisted or controlled ventilation. The narcotic antagonist naloxone hydrochloride is a specific antidote against respiratory depression which may result from overdosage or unusual sensitivity to narcotics, including oxycodone. Therefore, an appropriate dose of naloxone hydrochloride (usual initial adult dose 0.4 mg to 2 mg) should be administered preferably by the intravenous route and simultaneously with efforts at respiratory resuscitation (see package insert). Since the duration of action of oxycodone may exceed that of the antagonist, the patient should be kept under continued surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration.

An antagonist should not be administered in the absence of clinically significant respiratory or cardiovascular depression. Oxygen, intravenous fluids, vasopressors and other supportive measures should be employed as indicated.

Gastric emptying may be useful in removing unabsorbed drug.

## DOSAGE AND ADMINISTRATION

Dosage should be adjusted according to the severity of the pain and the response of the patient. It may occasionally be necessary to exceed the usual dosage recommended below in cases of more severe pain or in those patients who have become tolerant to the analgesic effect of narcotics. Oxycodone and Acetaminophen Tablets are given orally. The usual adult dosage is one tablet every 6 hours as needed for pain.

## HOW SUPPLIED

Oxycodone Hydrochloride and Acetaminophen Tablets, USP, 5 mg/325 mg, supplied as a white round tablet, with one face, scored debossed 4839 and V, and the other plain, are available in bottles of 10, 100, 500 and 1000.

Store at controlled room temperature 15°-30° C. (59° - 86° F).

DEA Order Form Required

**Vintage Pharmaceuticals, Inc.**
**Charlotte, NC 28206**

IN-70
Revised 5/96
Rev 3

# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER 040105

## CHEMISTRY REVIEW(S)

1. CHEMIST'S REVIEW NO. 4

2. ANDA # 40-105

3. NAME AND ADDRESS OF APPLICANT

Vintage Pharmaceuticals, Inc.
3241 Woodpark Boulevard
Charlotte, NC 28206

4. LEGAL BASIS FOR ANDA SUBMISSION

Reference drug product:
Percocet® (Acetaminophen/Oxycodone, 325 mg/5 mg - Dupont Pharmaceuticals, Inc.
No patents, AA product

5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME

7. NONPROPRIETARY NAME

Oxycodone and Acetaminophen Tablets USP, 5 mg/325 mg

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

Firm:

6-9-94: Original submission
8-10-94: Amendment
2-22-95: Amendment
4-19-95: Amendment
9-21-95: Amendment
3-28-96: Amendment in reference to the 3-28-96 telephone conversation.
4-02-96: Amendment
4-5-96: Labeling amendment
4-30-96: Amendment
5-30-96: Amendment
6-10-96: Amendment
6-20-96: Amendment
7-09-96: Amendment (withdrawal of [redacted] (b)4 - Confidential [redacted] as a source of Oxycodone HCL and a three year expiration date)
7-16-96: Amendment

FDA:

6-23-94: Acknowledgement
10-28-94: 1st NA letter
8-11-95: 2nd NA letter
4-29-96: 3rd NA letter
6-7-96: Phone NA conversation
6-26-96: Phone conversation to request to withdraw [redacted] c[redacted](b)4 - [redacted]c. as a source of Oxycodone HCL and a three year expiration date.
7-16-96: Phone NA conversation regarding total impurities NMT [redacted](b)4 in the COA for the finished product

10. PHARMACOLOGICAL CATEGORY

Analgesic for the relief of moderate to moderately severe pain.

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

[redacted]
(b)4 - Confidential Business

13. DOSAGE FORM

Tablets

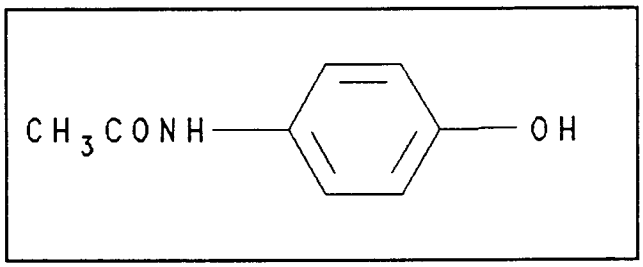
14. POTENCIES

5 mg/325 mg

15. CHEMICAL NAME AND STRUCTURE

Acetaminophen USP

$C_8H_9NO_3$; M.W. = 151.16




4'-Hydroxyacetanilide. CAS [103-90-2]

**Oxycodone Hydrochloride USP**

See USP 23 page 1129 for structure.

$C_{18}H_{21}NO_4 \cdot HCl$ 351.83

Morphinan-6-one, 4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-,hydrochloride, (5α)-,
4,5α-Epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride [124-90-3].

16. RECORDS AND REPORTS: N/A

17. COMMENTS

Comments:

Q: 1. Submit an accurate components statement for [redacted]

[redacted]/(b)4 - Confidential[redacted]

A: OK ( see Attachment I of 4-30-96 amendment).

Q: 2 We note that 10's and 500's were included in your application on the March 28, 1996 amendment. However, Your application fails to present complete descriptions of the container/closure systems. In that regard:

Q: a. Submit a description (in tabular form) containing the following information:

1) The manufacturer of the bottles for each package size (e.g., 10's, 100's, 500's and

1000's).
2) Names of all resins and materials to be used to manufacture the bottles and closures. Which resin will be used for manufacturing each size bottle?
3) Identify the manufacturer, supplier and composition for each component of your container/closure system.
4) The manufacturer of material used for inner seal.
5) The manufacturer of rayon or cotton, if applicable.
6) Which cap is used with which bottle?
7) Which bottle is used for each package size?
8) Which pigment is used in the resin for each size bottle and closure?
9) Do you use any desiccant for the container/closure systems?

This information may be referenced by authorization letters to DMF's, but you must provide a summary statement.

A: OK ( see Attachment II of 4-30-96 amendment).

Q: b. Submit the actual torque test for cap removal covering the 10's and 500's Tablets package sizes.

A: OK (see response 3 of 4-30-96 amendment). Torque testing was not conducted on the 10's and the 500's were not packaged.

Q: 3. We also note that there were no packaging batch records for bottles of 500 package size for lots #28103, 30103 and #29103. Please provide available records and justification for the partial packaging or, alternately, withdraw the bottle of 500.

A: OK (see response 4 of 4-30-96 amendment). Torque testing was not conducted on the 10's and the 500's were not packaged. Firm commitment to place units from the first three production batches on stability also pertains to the 500's.

**Status:**

a. **EER:** Satisfactory

Requested for applicant , [redacted] Lucia C. Tang on 10-8-94 and found acceptable on 12-16-

94. Updated and pr-approval EER was requested on 7-12-96 by Tim Ames with withdrawal of [redacted] Inc.

**b. MV** (method validation):

Satisfactory,

Active ingredient (Oxycodone HCl) and drug product are monographs in USP, Drug product test and release per USP XXII using monograph methods. However, methods verification has been again conducted by the FDA District Office and found acceptable on 8-28-95 by Kermit W. Henry.

**c. Bio-Review:** satisfactory

Bio-waiver OK. satisfactory reviewed on 7-26-94 per J. Chaney.

**d. Labeling review: Satisfactory**

Satisfactory per A Vezza and C. Hoppes reviewed on 6-11-96.

**e. DMFs: Satisfactory**

DMFs [redacted] were reviewed and found acceptable by L.Tang. DMF [redacted] was reviewed and found acceptable by L. Tang on 4/3/96.

18. CONCLUSIONS AND RECOMMENDATIONS

Approval

19. REVIEWER: DATE COMPLETED:

Lucia C. Tang 7-16-96

# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER 040105

## BIOEQUIVALENCE REVIEW(S)

JUL 27 1994

Oxycodone Hydrochloride/
Acetaminophen, USP
5 mg/325 mg Tablets
ANDA #40-105
Reviewer: James E. Chaney
WP# 40105DW.694

Vintage Pharmaceuticals, Inc.
Charlotte, NC
Submission Date:
June 9, 1994

Review of Dissolution Data and a Waiver Request

The firm has submitted comparative dissolution data in support of a request for a bioequivalence study waiver on its test product as provided for under 21 CFR 320.22. The listed drug is Percocet[R] (acetaminophen/oxycodone, 325 mg/5 mg) manufactured by DuPont Pharmaceuticals, Inc.

Comments:

1. The test drug product contains active ingredients in the same strength and dosage form as the currently approved reference product, DuPont Pharmaceuticals' Percocet[R] Tablets (acetaminophen/oxycodone, 325 mg/5 mg).

2. The dissolution method used was correct and satisfactory content uniformity data was submitted for the lot used in the dissolution testing.

3. The dissolution testing data demonstrate that the test and reference products meet the dissolution specifications (Table 1). The specifications are that not less than [redacted] of the labeled amount of oxycodone hydrochloride and not less than (b)(4) of the labelled amount of acetaminophen dissolve in 45 minutes. For both the test and reference products greater than [redacted] of the acetaminophen and greater than (b)(4) of the oxycodone hydrochloride are dissolved within 30 minutes.

4. The reference product, Percocet[R] (acetaminophen /oxycodone, 325 mg/5 mg) is classified AA in "Approved Drug Products with Therapeutic Equivalence Evaluations". Therefore, since the dissolution testing is acceptable there would be no need to conduct an *in vivo* bioequivalence study.

5. The formulation of the test product is given in Table 2.

6. The firm did not include %CV's in its dissolution report. The %CV's were calculated by the reviewer. In any future submissions of dissolution data the firm should report these values.

Recommendations:

1. The dissolution testing should be incorporated into the firm's manufacturing controls and stability program. The dissolution testing should be conducted in 900 mL of 0.1N HCL at 37°C using USP XXII apparatus II (paddle) at 50 rpm. The test product should meet the following specifications:

   Not less than (b)4 of the labeled amount of acetaminophen and oxycodone hydrochloride in the dosage form is dissolved in 45 minutes.

2. The dissolution testing conducted by Vintage Pharmaceuticals, Inc. on its drug product, oxycodone hydrochloride/acetaminophen tablet, 5 mg/325 mg (lot # 28103) has been found acceptable.

3. The Division of Bioequivalence agrees that the information submitted by Vintage Pharmaceuticals, Inc. on its drug product, oxycodone hydrochloride/acetaminophen tablet, 5 mg/325 mg falls under 21 CFR 320.22 of the Bioavailability/Bioequivalence Regulations. The waiver of in vivo bioequivalence study for the drug is granted. From the bioequivalence point of view, the Division of Bioequivalence deems oxycodone hydrochloride/acetaminophen tablets, USP, 5 mg/325 mg manufactured by Vintage Pharmaceuticals, Inc. to be bioequivalent to the reference product, Percocet[R] Tablets, 5 mg/325 mg manufactured by McNeil Laboratories.

The firm should be informed of the recommendations and comment 6.

/S/

James E. Chaney, Ph. D.
Division of Bioequivalence
Review Branch I

RD INITIALED AJACKSON
FT INITIALED AJACKSON /S/ Date: _____

cc: Anda 40-105 original, HFD-630, HFD-600 (OGD), HFD-604 (Hare), HFC-130 (Allen), HFD-652 (Wu, Chaney), Drug File

JEC/072794/ntp/WP #40105SW.694

**Table 1. In Vitro Dissolution Testing**

Drug (Generic Name): Oxycodone Hydrochloride/Acetaminophen
Dose Strength: 5 mg/325 mg
ANDA No.: ANDA # 40-105
Firm: Vintage Pharmaceuticals, Inc.
Submission Date: June 9, 1994
File Name: 40105DW.694

I. Conditions for Dissolution Testing:

USP XXII Basket: Paddle: X RPM: 50
No. Units Tested: 12
Medium: 0.1N HCl Volume: 900 ml
Specifications: NLT (b)4 of the oxycodone hydrochloride in 45 min,
NLT (b)4 of the acetaminophen in 45 min.
Reference Drug: Percocet Tablets, DuPont Pharmaceuticals, Inc.
Assay Methodology: (b)4

II. Results of In Vitro Dissolution Testing:

Oxycodone HCl

| Sampling Times (Minutes) | Test Product Lot # 28103 Strength(mg) 5 | | | Reference Product Lot # EA044A Strength(mg) 5 | | |
|---|---|---|---|---|---|---|
| | Mean % | Range | %CV | Mean % | Range | %CV |
| 5 | 68.4 | (b)4 - Confidential Business | 30 | 76.8 | (b)4 - Confidential Business | 17 |
| 15 | 96.5 | | 3.3 | 101.1 | | 5.6 |
| 30 | 97.7 | | 2.6 | 107.6 | | 3.4 |
| 45 | 97.3 | | 1.8 | 108.5 | | 2.5 |

Acetaminophen

| Sampling Times (Minutes) | Test Product Lot # 28103 Strength(mg) 325 | | | Reference Product Lot # EA044A Strength(mg) 325 | | |
|---|---|---|---|---|---|---|
| | Mean % | Range | %CV | Mean % | Range | %CV |
| 5 | 78.2 | (b)4 - Confidential Business | 17 | 34.4 | (b)4 - Confidential Business | 14 |
| 15 | 98.3 | | 3.2 | 65.4 | | 7.3 |
| 30 | 99.8 | | 2.9 | 81.8 | | 5.8 |
| 45 | 100.0 | | 2.0 | 87.9 | | 6.2 |

Table 2.

Formulation of Vintage Pharmaceuticals' Proposed Oxycodone Hydrochloride/Acetaminophen, 5 mg/325 mg Tablets

| Component | mg/Tablet |
|---|---|
| Acetaminophen Granulation | 361.1 |
| (b)4 - Confidential | |
| Equivalent to 325.0 mg of Acetamiophen USP) | |
| Oxycodone HCl, USP | 5.00 |
| Microcrystalline Cellulose, NF | (b)4 - |
| Sodium Starch Glycolate, NF | nfiden |
| Magnesium Stearate, NF | |
| Total Weight | 550.00 |

* Excipients used in (b)4 - Confidential Business